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Federal Agencies

June 2, 2004

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Art Unit 1654

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Continuation-in-Part Utility Patent Application Application No. 10/669,597; Filed: September 25, 2003

For: Polymer Conjugates with Decreased Antigenicity, Methods of

Propagation and Uses Thereof

Inventors:

MARTINEZ et al.

Our Ref:

2057.0040002/JAG/BJD

## Sir:

- Transmitted herewith for appropriate action are the following documents:
  - 1. Information Disclosure Statement;
  - 2. 15 sheets of Form PTO-1449;
  - 3. A copy of each of document nos. AO3, AF6 and AG6; and
  - 4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents June 2, 2004 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Attorney for Applicants Registration No. 42,473

BJD/nef Enclosures

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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MARTINEZ et al.

Appl. No.: 10/669,597

Filed: September 25, 2003

For: Polymer Conjugates with

Decreased Antigenicity, Methods of Preparation and Uses Thereof

Confirmation No.: 1312

Art Unit: 1654

Examiner: To be assigned

Atty. Docket: 2057.0040002/JAG/BJD

# **Information Disclosure Statement**

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of Doc. Nos. AO3, AF6 and AG6 are provided herewith. Copies of the remaining documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in U.S. Application No. 10/317,092, filed December 12, 2002, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. See 37 C.F.R. § 1.98(d).

In accordance with 37 C.F.R. §1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language documents, Doc. Nos. AL1 and AT6, cited on Form PTO-1449:

Document AL1, Japanese Patent Publication No. JP 55-99189, is in the Japanese language. An unverified English language abstract of document AL1 is cited as document AR15.

Document AT6, Iakunitskaia, L.M., et al., is in the Russian language. An unverified English language abstract of document AT6 can be found on page 237 of the publication

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Attorney for Applicants Registration No. 42,473

Date: Jul 2, 2004

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ATTY. DOCKET NO. 2057.0040002/JAG/BJD

APPLICATION NO. 10/669,597

APPLICANT MARTINEZ et al.

FILING DATE September 25, 2003 GROUP 1654

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,286,637	02/15/1994	Veronese et al.			07/26/1990
	AB1	5,880,225	03/09/1999	Yang et al.			07/15/1998
	AC1	6,245,901 B1	06/12/2001	von der Osten et al.			02/17/1998
	AD1	4,002,531	01/11/1977	Royer			01/22/1976
	AE1	4,179,337	12/18/1979	Davis et al.			07/28/1977
	AF1	4,609,546	09/02/1986	Hiratani			06/23/1983
	AG1	4,904,582	02/27/1990	Tullis			06/11/1987
	AH1	4,943,579	07/24/1990	Vishnuvajjala et al.			10/06/1987
	AI1	4,946,778	08/07/1990	Ladner et al.			01/19/1989
	AJ1	5,004,758	04/02/1991	Boehm et al.			11/02/1988
	AK1	5,006,333	04/09/1991	Saifer et al.			07/13/1989

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	JP 55-99189 A	07/28/1980	Japan			Yes X No
	AM1	WO 89/01033 A1	02/09/1989	WIPO			Yes No
	AN1	WO 95/00162 A1	01/05/1995	WIPO			Yes No
	A01	WO 95/13090 A1	05/18/1995	WIPO			Yes No
	AP1	WO 98/48837 A1	11/05/1998	WIPO			Yes No

		OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	1	Abuchowski, A., and Davis, F.F., "Soluble Polymer-Enzyme Adducts," in <i>Enzymes as Drugs</i> Holcenberg, J.S., et al., eds., John Wiley & Sons, Inc., New York, NY, pp. 367-383, (1981).
AS	1	Abuchowski, A., et al., "Cancer Therapy with Chemically Modified Enzymes. I. Antitumor Properties of Polyethylene Glycol-Asparaginase Conjugates," Cancer Biochem. Biophys. 7:175-186, Gordon and Breach Science Publishers, Inc. (1984).
AT	1	Abuchowski, A., et al., "Effect of Covalent Attachment of Polyethylene Glycol on Immunogenicity and Circulating Life of Bovine Liver Catalase," J. Biol. Chem. 252:3582-3586, American Society of Biological Chemists, Inc. (1977).

EXAMINER

DATE CONSIDERED

### INFORMATION DISCLOSURE STATEMENT

	<u> </u>
ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
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FILING DATE September 25, 2003	GROUP 1654

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,080,891	01/14/1992	Saifer et al.			08/01/1990
	AB2	5,093,531	03/03/1992	Sano et al.			05/05/1989
	AC2	5,252,714	10/12/1993	Harris et al.			11/28/1990
	AD2	5,283,317	02/01/1994	Saifer et al.			10/11/1991
	AE2	5,395,619	03/07/1995	Zalipsky et al.			03/03/1993
	AF2	5,428,128	06/27/1995	Mensi-Fattohi et al.			09/27/1994
	AG2	5,468,478	11/21/1995	Saifer et al.			10/18/1993
	AH2	5,476,653	12/19/1995	Pitt et al.			03/22/1995
	AI2	5,612,460	03/18/1997	Zalipsky			02/17/1994
	AJ2	5,621,039	04/15/1997	Hallahan et al.			06/08/1993
	AK2	5,622,986	04/22/1997	Greenwald et al.			10/19/1994

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 00/07629 A3	02/17/2000	WIPO			Yes No
	AM2	WO 00/12587 A2	03/09/2000	WIPO			Yes No
	AN2	WO 00/23798 A1	04/27/2000	WIPO			Yes No
	A02	WO 01/26692 A1	04/19/2001	WIPO			Yes No
	AP2	WO 01/59078 A2	08/16/2001	WIPO			Yes No

		OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	2	Akiyama, Y., et al., "Selective Synthesis of Heterobifunctional Poly(ethylene glycol) Derivatives Containing Both Mercapto and Acetal Terminals," Bioconj. Chem. 11:947-950 American Chemical Society (2000).
AS	2	Arakawa, T., et al., "Reversibility of Acid Denaturation of Recombinant Interferon-Y, Biopolymers 29:1065-1068, John Wiley & Sons, Inc. (1990).
AT	2	Beauchamp, C.O., et al., "A New Procedure for the Synthesis of Polyethylene Glycol-Protein Adducts; Effects on Function, Receptor Recognition, and Clearance of Superoxide Dismutase, Lactoferrin, and $\alpha_2$ -Macroglobulin, "Anal. Biochem. 131:25-33, Academic Press, Inc. (1983).

EXAMINER

DATE CONSIDERED

INFORMATION DISCLOSURE STATEMENT

	Fage 3 01 13
ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	5,643,575	07/01/1997	Martinez et al.			10/27/1993
	AB3	5,672,662	09/30/1997	Harris et al.			10/02/1995
	AC3	5,728,560	03/17/1998	Shorr et al.			06/14/1996
	AD3	5,730,990	03/24/1998	Greenwald et al.			06/05/1995
	AE3	5,738,846	04/14/1998	Greenwald et al.			11/21/1995
	AF3	5,766,897	06/16/1998	Braxton			04/21/1995
	AG3	5,811,076	09/22/1998	Brasch et al.			05/19/1994
	АН3	5,824,701	10/20/1998	Greenwald et al.			02/03/1997
	AI3	5,840,900	11/24/1998	Greenwald et al.			08/20/1996
	AJ3	5,880,131	03/09/1999	Greenwald et al.			09/29/1995
	АКЗ	5,900,402	05/04/1999	Shorr			05/29/1997

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 02/094853 A2	11/28/2002	WIPO			Yes No
	AM3	WO 03/002716 A2	01/09/2003	WIPO			Yes No
	AN3	WO 03/011211 A2	02/13/2003	WIPO			Yes No
	A03	WO 04/030617 A2	04/15/2004	WIPO .			Yes No
	AP3						Yes No

 	<del> </del>	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	3	Benhar, I., et al., "Mutations of Two Lysine Residues in the CDR Loops of a Recombinan Immunotoxin That Reduce Its Sensitivity to Chemical Derivatization," Bioconj. Chem. 5:321-326, American Chemical Society (1994).
AS	3	Bentley, M.D., et al., "Reductive Amination Using Poly(ethylene glycol) Acetaldehyde Hydrate Generated in Situ: Applications to Chitosan and Lysozyme," J. Pharm. Sci. 87:1446-1449, American Chemical Society and American Pharmaceutical Association (1998)
AT	3	Blake, M.S., et al., "A Rapid, Sensitive Method for Detection of Alkaline Phosphatase-Conjugated Anti-antibody on Western Blots," Anal. Biochem. 136:175-179, Academic Press, Inc. (1984).

EXAMINER

DATE CONSIDERED

INFORMATION DISCLOSURE STATEMENT

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U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA4	5,902,588	05/11/1999	Greenwald et al.			11/19/1997	
	AB4	5,919,455	07/06/1999	Greenwald et al.			03/20/1997	
	AC4	5,932,462	08/03/1999	Harris et al.			05/17/1995	
<u> </u>	AD4	5,951,974	09/14/1999	Gilbert et al.			12/19/1997	
	AE4	5,965,119	10/12/1999	Greenwald et al.			12/30/1997	
	AF4	5,965,566	10/12/1999	Greenwald et al.			08/20/1997	
	AG4	5,969,040	10/19/1999	Hallahan et al.			12/13/1996	
	AH4	5,981,709	11/09/1999	Greenwald et al.			12/19/1997	
	AI4	5,990,237	11/23/1999	Bentley et al.			05/20/1998	
	AJ4	6,011,042 B1	01/04/2000	Greenwald et al.			10/10/1997	
	AK4	6,042,822	03/28/2000	Gilbert et al.			04/06/1999	

September 25, 2003

	FOREIGN PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION		
	AL4						Yes No		
	AM4						Yes No		
	AN4						Yes No		
	A04						Yes No		
	AP4						Yes No		

	<del></del>	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	4	Brenner, B.M., et al., "Glomerular permselectivity: barrier function based on discrimination of molecular size and charge," Am. J. Physiol. 234:F455-F460, American Physiological Society (1978).
AS	4	Cheng, TL., et al., "Efficient Clearance of Poly(ethylene glycol)-Modified Immunoenzyme with Anti-PEG Monoclonal Antibody for Prodrug Cancer Therapy," Bioconj. Chem. 11:258-266, American Chemical Society (2000).
AT	4	Cheng, TL., et al., "Accelerated Clearance of Polyethylene Glycol-Modified Proteins by Anti-Polyethylene Glycol IgM," <i>Bioconj. Chem.</i> 10:520-528, American Chemical Societ (1999).

EXAMINER

DATE CONSIDERED

INFORMATION DISCLOSURE STATEMENT

	1490 3 01 13
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U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE	
	AA5	6,113,906	09/05/2000	Greenwald et al.			12/29/1998	
	AB5	6,127,355	10/03/2000	Greenwald et al.			03/26/1999	
	AC5	6,132,713	10/17/2000	Fiipula et al.			03/18/1999	
	AD5	6,132,763	10/17/2000	Fisher			06/02/1995	
	AE5	6,177,087 B1	01/23/2001	Greenwald et al.			11/03/1998	
	AF5	6,180,095 B1	01/30/2001	Greenwald et al.			10/30/1998	
	AG5	6,239,262 B1	05/29/2001	Cramer et al.			12/30/1998	
	AH5	RE 32,518	10/13/1987	Miyasaka et al.			11/29/1984	
	AI5	2001/0028881 A1	10/11/2001	Roffler et al.			03/16/2001	
	AJ5	2002/0052443 A1	05/02/2002	Greenwald et al.			04/07/2000	
	AK5	2002/0061307 A1	05/23/2002	Whitlow et al.			02/26/2001	

FOREIGN PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
	AL5						Yes No	
	AM5						Yes No	
	AN5						Yes No	
	A05						Yes No	
	AP5						Yes No	

γ		OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	<u>5</u>	Clark, R., et al., "Long-acting Growth Hormones Produced by Conjugation with Polyethylene Glycol," J. Biol. Chem. 271:21969-21977, The American Society for Biochemistry and Molecular Biology, Inc. (1996).
AS	<u>5</u>	Davis, S., et al., "Alteration of the circulating life and antigenic properties of bovine adenosine deaminase in mice by attachment of polyethylene glycol," Clin. Exp. Immunol. 46:649-652, Blackwell Scientific Publications (1981).
AT	<u>5</u>	Fuke, I., et al., "Synthesis of poly(ethylene glycol) derivatives with different branchings and their use for protein modification," J. Control. Rel. 30:27-34, Elsevi Science B.V. (1994).

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DATE CONSIDERED

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ATTY. DOCKET NO. 2057.0040002/JAG/I	зло	APPLICATION NO. 10/669,597
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U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	маме	CLASS	SUB-CLASS	FILING DATE	
	AA6	2002/0072573 A1	06/13/2002	Bentley et al.			02/08/2002	
	AB6	2002/0098192 A1	07/25/2002	Whitlow et al.			02/26/2001	
	AC6	2003/0012777 A1	01/16/2003	Sherman et al.			06/28/2002	
	AD6	4,434,228	02/28/1984	Swann			04/20/1982	
	AE6	2003/0082786 A1	05/01/2003	Ensor et al.			08/02/2001	
	AF6	2003/0153694 A1	08/14/2003	Rosen et al.			11/25/2002	
	AG6	2004/0034188 A1	02/19/2004	Rosen et al.			05/07/2003	
	AH6							
	AI6							
	AJ6							
	AK6							

FOREIGN PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
	AL6						Yes No	
	AM6						Yes No	
	AN6						Yes No	
	A06						Yes No	
	AP6						Yes No	

	1	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	<u>6</u>	Harris, J.M., et al., "Synthesis and Characterization of Poly(ethylene glycol) Derivatives," J. Polymer Sci. 22:341-352, John Wiley & Sons, Inc. (1984).
AS	<u>6</u>	Hershfield, M.S., et al., "Treatment of Adenosine Deaminase Deficiency with Polyethylene Glycol-Modified Adenosine Deaminase," N. Engl. J. Med. 316:589-596, Massachusetts Medical Society (1987).
AT	<u>6</u>	Iakunitskaia, L.M., et al., "Preparation of Subtilisin BPN' and Dextrane Conjugates Prikl. Biokhim. Mikrobiol. 16:232-237, Nauka (1980).

EXAMINER

DATE CONSIDERED

# INFORMATION DISCLOSURE STATEMENT

	1490 / 01 15
ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
APPLICANT MARTINEZ et al.	
FILING DATE September 25, 2003	GROUP 1654

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA7						
	AB7						
	AC7						
	AD7						
	AE7						
	AF7						
	AG7						
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_	AI7						
	AJ7						
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	FOREIGN PATENT DOCUMENTS						
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL7						Yes No
	AM7 ·						Yes No
	AN7						Yes No
	A07						Yes No
	AP7						Yes No

			OTHER (Including Author, Title, Date, Pertinent Pages, etc.)	
	AR	2	Kelly, S.J., et al., "Diabetes Insipidus in Uricase-Deficient Mice: A Evaluating Therapy with Poly(Ethylene Glycol)-Modified Uricase," J. 12:1001-1009, Lippincott Williams & Wilkins (May 2001).	
	AS	7	Kocienski, P.J., "2.4.4 Trityl Ethers," in <i>Protecting Groups, 1<sup>st</sup> edi</i> Verlag, Stuttgart, Germany, pp. 54-55 and 260 (1994).	tion, Georg Thieme
	AT	7	Kito, M., et al., "A Simple and Efficient Method for Preparation of Monomethoxypolyethylene Glycol Activated with p-Nitrophenylchloroform Application to Modification of L-Asparaginase," J. Clin. Biochem. Nut Institute of Applied Biochemistry (1996).	
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INFORMATION	DISCLOSURE	STATEMENT

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ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
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<u> </u>	U.S. PATENT DOCUMENTS						
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA8						
	AB8						
	AC8						
	AD8						
	AE8						
	AF8						
	AG8						
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	AI8						
	AJ8						
	AK8						

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL8						Yes No
	AM8						Yes No
	AN8						Yes No
	A08						Yes No
	AP8						Yes No

	1	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	8	Kuwabara, T., et al., "Renal Clearance of a Recombinant Granulocyte Colony-Stimulating Factor, Nartograstim, in Rats," <i>Pharm. Res.</i> 12:1466-1469, Plenum Publishing Corporation (1995).
AS	8	Marie, A., et al., "Characterization of Synthetic Polymers by MALDI-TOF/MS: Investigation into New Methods of Sample Target Preparation and Consequence on Mass Spectrum Finger Print," Anal. Chem. 72:5106-5114, American Chemical Society (2000).
АТ	8	Merrill, E.W., "Poly(ethylene oxide) star molecules: Synthesis, characterization, and applications in medicine and biology," <i>J. Biomater. Sci. Polymer Edn.</i> 5:1-11, VSP (1993).

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	1490 7 01 15
ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA9						
	AB9						
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	AF9						
	AG9						
	АН9						
	AI9						
	АЛ9						
	AK9						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL9						Yes No
	AM9						Yes No
	AN9						Yes No
	A09						Yes No
_	AP9						Yes No

1	-T	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	9	Mordenti, J., et al., "Interspecies Scaling of Clearance and Volume of Distribution Data for Five Therapeutic Proteins," Pharm. Res. 8:1351-1359, Plenum Publishing Corporation (1991).
AS	9	Narhi, L.O., et al., "Stoichiometric Complexation of Streptomyces Subtilisin Inhibit and Subtilisin," <i>J. Prot. Chem.</i> 10:385-389, Plenum Publishing Corporation (1991).
AT	9	Pui, CH., et al., "Recombinant Urate Oxidase for the Prophylaxis or Treatment of Hyperuricemia in Patients With Leukemia or Lymphoma," J. Clin. Oncol. 19:697-704, American Society of Clinical Oncology (February 2001).

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# INFORMATION DISCLOSURE STATEMENT

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ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
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U.S. PATENT DOCUMENTS												
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE					
	AA10											
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FOREIGN PATENT DOCUMENTS											
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION				
	AL10						Yes No				
	AM10						Yes No				
	AN10						Yes No				
	A010						Yes No				
	AP10						Yes No				

		1	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
	AR	10	Richter, A.W., and Åkerblom, E., "Antibodies against Polyethylene Glycol Produced in Animals by Immunization with Monomethoxy Polyethylene Glycol Modified Proteins," Int Archs. Allergy Appl. Immunol. 70:124-131, S. Karger AG (1983).
	AS	10	Rocca, M., et al., "Pathophysiological and histomorphological evaluation of polyacryloylmorpholine vs polyethylene glycol modified superoxide dismutase in a rat model of ischaemia/reperfusion injury," Int. J. Artif. Organs 19:730-734, Wichtig Editore (1996).
	AT	10	Saifer, M.G.P., et al., "Improved Conjugation of Cytokines Using High Molecular Weigh Poly(ethylene glycol): PEG-GM-CSF as a Prototype," Polymer Preprints 38:576-577, American Chemical Society (1997).
XAMINER			DATE CONSIDERED

**BEAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to

Applicant.

### INFORMATION DISCLOSURE STATEMENT

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	ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
	APPLICANT MARTINEZ et al.	
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U.S. PATENT DOCUMENTS											
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE				
	AA11										
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	AL11						Yes No			
	AM11						Yes No			
	AN11						Yes No			
	A011						Yes No			
	AP11						Yes No			

			OTHER (Including Author, Title, Date, Pertinent Pages, etc.	)			
	AR	11	Sakane, T., and Pardridge, W.M., "Carboxyl-directed Pegylati Neurotrophic Factor Markedly Reduces Systemic Clearance with Activity," Pharm. Res. 14:1085-1091, Plenum Publishing Corpo	Minimal Loss of Biologic			
·	AS	11	Sayle, R.A., and Milner-White, E.J., "RASMOL: bimolecular gr Biochem. Sci. 20:374-376, International Union of Biochemistr (1995).				
Sharp, K.A., et al., "Synthesis and Application of a Poly(ethylene glycol)-Affinity Ligand for Cell Separations in Aqueous Polymer Two-Phase Systems,"  Biochem. 154:110-117, Academic Press, Inc. (1986).							
KAMINER			ı	DATE CONSIDERED			

INFORMATION DISCLOSURE STATEMENT

EXAMINER

ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
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U.S. PATENT DOCUMENTS												
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE					
	AA12											
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION					
	AL12						Yes No					
	AM12						Yes No					
	AN12						Yes No					
	A012						Yes No					
	AP12						Yes No					

- I	1	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	12	Sherman, M.R., et al., "Conjugation of High-Molecular Weight Poly(ethylene glycol) to Cytokines: Granulocyte-Macrophage Colony-Stimulating Factors as Model Substrates," in Poly(ethylene glycol): Chemistry and Biological Applications, Harris, J.M., and Zalipsky, S., eds., American Chemical Society, Washington, DC, pp. 155-169 (1997).
AS	12	Suzuki, T., et al., "Physicochemical and Biological Properties of Poly(ethylene glycol)-Coupled Immunoglobulin G," Biochem. Biophys. Acta 788:248-255, Elsevier Science B.V. (1984).
AT	12	Tsai, NM., et al., "Sensitive Measurement of Polyethylene Glycol-Modified Proteins, BioTechniques 30:396-400 and 402, Eaton Publishing Co. (February 2001).

#### INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2057.0040002/JAG/BJD APPLICATION NO. 10/669,597

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U.S. PATENT DOCUMENTS									
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	AA13								
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION			
	AL13						Yes No			
4.144	AM13						Yes No			
	AN13						Yes No			
	A013						Yes No			
	AP13						Yes No			

 	т—	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
AR	13	Tsang, V.C.W., et al., "Calibration of Prestained Protein Molecular Weight Standards for Use in the 'Western' or Enzyme-Linked Immunoelectrotransfer Blot Techniques," Ana. Biochem. 143:304-307, Academic Press, Inc. (1984).
AS	13	Venkatachalam, M.A., and Rennke, H.G., "The Structural and Molecular Basis of Glomerular Filtration," <i>Circ. Res.</i> 43:337-347, Grune & Stratton (1978).
AT	13	Veronese, F.M., et al., "Surface Modification of Proteins. Activation of Monomethoxy-Polyethylene Glycols by Phenylchloroformates and Modification of Ribonuclease and Superoxide Dismutase," Appl. Biochem. Biotech. 11:141-152, The Human. Press Inc. (1985).

EXAMINER

DATE CONSIDERED

### INFORMATION DISCLOSURE STATEMENT

	1436 11 01 13
ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
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U.S. PATENT DOCUMENTS									
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE		
	AA14								
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION			
	AL14						Yes No			
	AM14						Yes No			
	AN14						Yes No			
	A014						Yes No			
	AP14						Yes			

		<u>1</u>	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
	AR	14	von Specht, BU., et al., "Polyvinylpyrrolidone as a Soluble Carrier of Proteins," Hoppe-Seyler's Z. Physiol. Chem. 354:1659-1660, Walter de Gruyter (1973).
	AS	14	Wilchek, M., et al., "Affinity Chromatography," Meth. Enzymol. 104:3-55, Academic Press, Inc. (1984).
	AT	14	Wilson, G., et al., "Selective Hepatic Uptake of Synthetic Glycoproteins.  Mannosaminated Ribonuclease A Dimer and Serum Albumin," J. Gen. Physiol. 74:495-509,  The Rockefeller University Press (1979).
XAMINER			DATE CONSIDERED

## INFORMATION DISCLOSURE STATEMENT

_		1490 13 01 13
	ATTY. DOCKET NO. 2057.0040002/JAG/BJD	APPLICATION NO. 10/669,597
	APPLICANT MARTINEZ et al.	
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U.S. PATENT DOCUMENTS									
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE		
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION			
	AL15						Yes No			
	AM15						Yes No			
	AN15						Yes No			
	A015						Yes No			
	AP15		·				Yes No			

			OTHER (Including Author, Title, Date, Pertinent Pages, etc.	.)
	AR	<u>15</u>	Unverified English language abstract for Japanese Patent Po Document AL1, Japan Patent Office (accessed via Internet of	
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